REMARKS

Claims 1-36 are pending in the present application. Claims 16-35 have previously been withdrawn. In the Office Action mailed December 17, 2003, the Examiner rejected claims 1, 2, 11-13, and 36 under 35 U.S.C. §102(b) as being clearly anticipated by Murphy (WO 98/40009). Next, the Examiner rejected claims 1-3, 7, 9, and 36 under 35 U.S.C. §102(b) as being anticipated by Saltzstein et al. (USP 5,704,364). Claims 1, 2, 4-6, 11-13, and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bornn (USP 5,564,429). Claims 1, 2, and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over David et al. (USP 5,544,649). Claims 3 and 7-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bornn (or David et al., Saltzstein et al., or Murphy). Claims 14 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bornn (or David et al., Saltzstein et al., or Murphy) in view of Morgan et al. (5,782,878).

FINALITY OF ACTION

The Examiner made the Office Action of 12/17/03 Final. Applicant seeks reconsideration. The Examiner rejected claims 1, 2, 11-13, and 36 under 35 U.S.C. §102(b) as being clearly anticipated by Murphy (WO 98/40009). In responding to Applicant's arguments filed in the Response of 10/23/03, the Examiner states that "[t]he argument that the examiner 'must' provide an explanation at the end of the paragraph for a 102 or 103 rejection is not persuasive since the MPEP does not state this."

MPEP §706.02(i), which is titled "Form paragraphs for use in rejections Under 35 U.S.C. 102", states:

> ¶ 7.15 Rejection, 35 U.S.C. 102(a), (b) Patent or Publication, and (g)
> Claim [1] rejected under 35 U.S.C. 102[2] as being [3] by [4].
> Examiner Note:
>
> 1. In bracket 2, insert the appropriate paragraph letter or letters of 35 U.S.C. 102 in parentheses. If paragraph (e) of 35 U.S.C. 102 is applicable, use form paragraph 7.15.02 or 7.15.03.
>
> 2. In bracket 3, insert either --clearly anticipated-- or --anticipated-- **with an explanation at the end of the paragraph**. (emphasis added).

Merely stating that the claims are rejected as being clearly anticipated by a reference does little to further prosecution of the pending application. "The goal of examination is to clearly articulate any rejection early in the prosecution process so that the Applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity." MPEP §706 (emphasis added). As such, by merely rejecting the claims of the

above captioned application without any explanation of the applicability of the reference to the pending claims, the Examiner did not develop a clear issue regarding the patentability of the present claims.

"The Applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application." MPEP §706.07. Although likely unintentioned, in failing to provide Applicant an explanation of the applicability of Murphy to the claims of the pending application, the Examiner prematurely cut off Applicant in the prosecution of the present application. At least for those reasons outlined above, and as supported by the MPEP, the finality of the present action is believed premature. As such, Applicant requests that the finality of the pending action be withdrawn.

REJECTIONS

The Examiner rejected claims 1, 2, 11-13, and 36 under 35 U.S.C. §102(b) as being clearly anticipated by Murphy (WO 98/40009). The Examiner has now also provided a marked-up copy of the reference (which is appreciated), but has not made further explanation of the markings to the elements of the pending claims. Consistent with the Examiner's recommendation, claim 1 has been amended to clarify the integration of the wireless communication interface and the ECG monitor. As amended, claim 1 calls for, in part, a portable ECG device having a wireless communication interface integral to the ECG monitor to receive patient ECG data from the ECG monitor and capable of transmitting patient ECG data and video to a remote health care provider. Based on this recommendation by the Examiner, Applicant believes claim 1, and those claims that depend therefrom, are in condition for allowance.

Further, it is clear that the device of Murphy does not transmit video as called for in claims 1 and 36. Murphy teaches transmission of still pictures "grabbed" from a video camera. Murphy p. 3, lns. 21-24, p. 8, lns 7-13, and p. 14, lns. 19-27. While Murphy teaches the use of a video camera for providing "moving images of the patient on the head up display and LCD display," it is clear that only still images "grabbed" from the video are transmitted "to the medical expert at the remote location." Murphy p. 8, lns. 8-12. That is, Murphy appreciates the distinction between "video" and a "still image". The Examiner's statement that Applicant has not used the term "moving video" to define over Murphy is not supported in the reference. Simply, Murphy teaches transmitting a still image captured from video – not transmitting video as called for in claims 1 and 36.

Therefore, unlike the claimed invention, Murphy teaches a wireless communications interface that is only capable of transmitting intermittent still pictures of the patient. On the other hand, claims 1 and 36 are clear that the wireless communications interface can transmit data and video. Accordingly, since "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131. Claims 1 and 36, and those claims that depend therefrom, are patentably distinct over Murphy.

The Examiner rejected claims 1-3, 7, 9, and 36 under 35 U.S.C. §102(b) as being anticipated by Saltzstein et al. stating that "Salzstein [sic] states that the system can all be used in a PC which provides the integrated monitor, processor, and interface and is inherently portable since it is a PC." Claims 1 and 36 call for a portable ECG-device. As stated in the specification, "To provide simplicity of use, the system should not require the patient to remember a phone number and require dialing the phone number when the patient is in the middle of experiencing chest pains, and preferably, there should be no extra device to plug into a wall outlet which may be time-consuming and difficult for some patients when experiencing ischemic symptoms." Pg. 3, lns 10-15. Additionally, both claims 1 and 36 call for, in part, a wireless communication interface capable of wirelessly transmitting patient data and voice or video to a health care provider. That is, the device is patient portable and is not tethered to a communication system. It is apparent that the device of Saltzstein et al. while being movable, is not portable as that term is used in the present application. Further, the prior art does not show a "wireless interface" that transmits to the remote health care provider.

Saltzstein et al. states that "[a] life signs monitor at the patient site is connected to the patient and to a DSVD device having the ability to digitize and compress the patient's voice and having the ability to decompress and render in analog form the physician's voice via a standard telephone." (emphasis added) Col. 2, lns. 45-49. That is, the patient is tethered to a phone line and while the device is movable, it is not portable as it's range of motion is limited by the amount of available phone line. Saltzstein et al. reiterates that "[a]t a patient site indicated generally at 12, a patient 14 is operatively connected to a life signs monitor 16, ... [that] is operatively connected with a digital simultaneous voice and data (DSVD) device 18 that is capable of digitizing, compressing and time interleaving voice and data for transmission via a modem 20 over a single telephone line 22." (emphasis added) Col. 3, lns. 24-40. That is, the transmission of voice and data from the ECG device to the remote center occurs over a telephone wire.

Although Saltzstein et al. discloses that "[l]ife signs monitor 16 alternatively may be worn by patient 14 as a neck-worn pendant or wrist-worn watch, and it may wirelessly communicate patient data to DSVD device 18.", col. 5, lns. 50-53, digital simultaneous voice and data (DSVD) device 18 is not a remote health care provider. That is, the only wireless transmission of Saltzstein et al. occurs between the monitor and a DSVD device 18 located proximate the patient. The DSVD then sends the wirelessly received data to the remote provider via standard telephone lines. As such, the mobility of the patient is still limited by the range of the connectivity between the DSVD device and the life signs monitor 16. Simply, the patient is tethered by the connectivity between the life signs monitor and either a conventional phone line, or the range of communication of the DVSD device. Therefore, although the device of Saltzstein et al. is movable, it is by no means "portable" as that term is used in the present claims. By having a wireless interface between the portable device and the health care provider, the portability of the device of the present application is not tethered by the range of connectivity of a DSVD device or a physical telephone line. As such, that which is called for in claims 1 and 36, and those claims that depend therefrom, are patentably distinct over Saltzstein et al.

The Examiner next rejected claims 1, 2, 4-6, 11-13, and 36 under 35 U.S.C. §103(a) as being unpatentable over Bomn et al. stating that "Bomn discloses the claimed invention including using different configurations of electrodes except for the 12 lead wire assembly and processing." Applicant respectfully disagrees.

The burden of establishing a prima facie case of obviousness falls on the Examiner. MPEP §2142. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a prima facie case, the Examiner must not only show that the combination includes each and every element of the claimed invention, but also provide "a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). That is, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." MPEP §2143.01. "The fact that references can be combined or modified is not sufficient to establish prima facie obviousness." Id. When prior art references require a selected combination to render

obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988).

The Examiner's rejection does not address each and every element of the claims. As the Examiner states, Bomn et al. does not disclose each and every element of the claims. Specifically, Bomn et al. does not disclose a 12-lead wire assembly to acquire ECG data or a system that is on-demand.

Claims 1 and 36 explicitly state that the ECG monitor is "on-demand". However, the Examiner failed to address this element when rejecting the claims. Rather than addressing the elements of the claims in light of what is shown in the reference, the Examiner states that "[i]t is questioned whether the Applicant has specification support for the use of 'on-demand'". Such an assertion without a rejection merely hinders prosecution of the present application. Regardless, as the specification states at page 9, lines 7-10, "[t]he use of the ECG device starts when the patient experiences symptoms 104. If the patient is not familiar with using the device and the overall process 106, 108, the patient telephones the hospital 110 to acquire step by step instructions once symptoms appear." Simply, the device only needs to be worn when the patient experiences symptoms and has a demand for the monitoring. That is, the device is operable on-demand, as one skilled in the art would readily find apparent from the teachings of the present application.

Bomn et al. clearly teaches that the patient must wear "a torso band and an optional shoulder band" at all times. Col. 4, lns. 5-6. That is, if the patient moves beyond the communications range of the system or removes the torso band, the monitor will enter an alert condition. Col. 3, lns. 15-52 and Col. 4, lns. 3-25. The patient must then reenter the communications range and/or replace the torso band within a predetermined time interval in order to avoid sending an emergency notification. Col. 3, lns 15-25. Simply, the ECG monitor taught in Bomn is not on-demand because a patient does not have the option to use the ECG monitor at his or her discretion. Simply, the patient is required to continuously wear the torso band and stay within the bounds of operating conditions. Therefore, Bomn et al. clearly teaches a continuous and mandatory ECG monitor, not an on-demand monitor, as claimed. Accordingly, the prior art reference does not teach or suggest all the claim limitations.

Additionally, the Examiner acknowledged that Bomn et al. does not disclose the use of a 12-lead configuration or processing of 12-lead ECG data but asserts modifying Bomn et al. to include such would have been obvious. However, "[a] prima facie case of obviousness

may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention." MPEP §2144.05. Bomn et al. teaches away from the reception of data from the patient in a standard 12-lead configuration and the production of standard 12-lead ECG data by teaching the use of "pairs of electrodes" in various configurations. Col. 9, lns. 10-30 and Col. 10, lns. 1-6. One skilled in the art will immediately recognize that use of "pairs of electrodes" is indicative of bi-polar electrodes, which teaches away from a 12-lead ECG configuration because the 12-lead ECG configuration requires uni-polar electrodes. Thus, Bomn et al. teaches away from a 12-lead configuration by teaching a system that is not capable of a standard 12-lead ECG data acquisition. As such, at least for the reasons stated above, claims 1 and 36, and those claims that depend therefrom, are patentably distinct over Bomn et al.

The Examiner next rejected claims 1, 2, and 36 under 35 U.S.C. §103(a) over David et al. stating that "David discloses the claimed invention including except for the 12 lead wire assembly and processing." The Examiner continues concluding that it would have been obvious to modify David et al. to include 12 lead wire ECG monitoring.

Claims 1 and 36, individually in part, call for "a portable, on-demand ECG monitor." However, the system disclosed in David et al. is incapable of portability. Applicant does not necessarily disagree that the system of David et al. is remote from a traditional health care facility, however, it is apparent the device of David et al. is not portable. Applicant does not disagree that the device of David et al. is as moveable as any other piece of furniture, however, a piece of furniture is certainly not believed to be portable. A person of ordinary skill in the art would not interpret a couch or arm chair to be portable, as in a portable ECG device. Applicant hardly believes that one skilled in the art would consider the chair shown in Fig. 10 of David et al. to be "portable." Yes, it is movable, but just because something is movable, does not make it portable. Additionally, David et al. teaches a system utilizing cable television. One of ordinary skill in the art will readily recognize that not only is a connection to cable by definition not portable, the equipment required for cable television is too cumbersome to support portability. As such, David et al. teaches directly away from "a portable, on-demand ECG monitor."

Claims 1 and 36, also both individually call for, in part, a wireless communication interface between the ECG monitor and the health care provider. Specifically, claim 36 calls for, in part, a wireless communication interface capable of concurrently transmitting patient ECG data and voice data to a health care provider in a wireless transmission. Although David et al. discloses a wireless transmission between the patient and a receiver, David et al. states that "[t]he receiver 122 is typically in the patient's home." Col. 19, lns. 24-25.

David et al. further states that "[t]he receiver 122 also includes a transmission unit 128 which in turn transmits the data directly to the central station 20 preferably through the telephone lines." Col. 19, lns. 29-32. As such, the device of David et al. does not allow wireless communication to a health care provider. Additionally, similar to the device of Saltzstein et al., the patient is tethered to the transmission unit to ensure connectivity with the health care provider. That is, the device of David et al., although movable about a patient's home, is far from the degree of portability that allows wireless communication with the health care provider as called for in the claims. Therefore, that which is called for in claims 1 and 36, and the claims that depend therefrom, are patentably distinct over David et al.

The Examiner next rejected claims 3 and 7-10 under 35 U.S.C. §103(a) over Bomn (or David et al., Saltzstein et al., or Murphy) and claims 14 and 15 under 35 U.S.C. §103(a) over Bomn (or David et al., Saltzstein et al., or Murphy) in view of Morgan.

The Examiner has merely reiterated a blanket rejection previously presented in the Office Action of 7/17/2003 albeit with the addition of Saltzstein et al. Such a rejection is not sustainable on its face as being indefinite. The Examiner rejected claims 3, 7-10, 14 and 15 without specifically addressing each and every element of each and every claim and without even stating which reference is actually being relied upon. Applicant cannot be charged with responding to such an open ended rejection. Furthermore, when substantiating the rejection, the Examiner merely states that "Bomn (or David, Saltzstein et al, or Murphy) discloses the claimed invention..." but then fails to provide any support for the Examiner's interpretation of each reference or show how the Examiner's interpretation applies to each and every element of each and every claim. Applicant appreciates the Examiner's providing marked-up copies of the art of record; however, merely providing the Applicant with the references applied is not the same as the Examiner articulating his application of the references to the claims at issue as is required under MPEP §2143. As the MPEP sets forth:

> "When the motivation to combine the references is not immediately apparent, it is the duty of the Examiner to explain why the combination of the teachings is proper. [citation omitted]. A statement of a rejection that includes a large number of rejections must explain with reasonable specificity at least one rejection, otherwise the Examiner procedurally fails to establish a prima facie case of obviousness." MPEP §2142.

Merely providing the references with no additional explanation lacks the reasonable specificity required to support the Examiner's rejection of the claims. As such, the Examiner has not substantiated the Examiner's position with support from the cited references and, accordingly, has not met any of the three prongs required under MPEP §2143.

Additionally, since claim 1 has been amended to more accurately define that the wireless communication interface is integral to the ECG monitor, claims 3, 7-10, 14 and 15 are believed to be in condition for allowance at least pursuant to the chain of dependency.

Therefore, in light of the foregoing, Applicant respectfully believes that the present application is in condition for allowance. As a result, Applicant respectfully requests timely issuance of a Notice of Allowance for claims 1-15 and 36.

Applicant appreciates the Examiner's consideration of these Amendments and Remarks and cordially invites the Examiner to call the undersigned, should the Examiner consider any matters unresolved.

Respectfully submitted,

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Dated: February 17, 2004
Attorney Docket No.: GEMS8081.040

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